IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE:	)	
AREDIA® AND ZOMETA® PRODUCTS	)	
LIABILITY LITIGATION	)	
	)	
This Document Relates to Case Numbers:	)	
3-06-0388 (Wilson)	)	
3-06-0392 (Stevens)	)	NO. 3-06-1760
3-06-0493 (Chiles)	)	JUDGE CAMPBELL/BROWN
3-06-0494 (Krause)	)	
3-06-0516 (King)	)	
3-06-0554 (Worthington)	)	
3-06-0662 (Dore)	)	
3-06-0693 (Nightlinger)	)	
3-08-0070 (Davids)	)	
3-08-0909 (Evers)	)	
3-08-0934 (Hill)	)	

ORDER SUMMARIZING MDL 1760 PROCEEDINGS UPON SUGGESTION OF REMAND

This Order Summarizing MDL 1760 Proceedings Upon Suggestion of Remand is intended to guide the transferor court upon remand of an individual case previously consolidated with MDL 1760. This Order summarizes the events that have taken place in MDL 1760 and further supports the Court's Order Suggesting Remand. A copy of this Order will be provided to the transferor court upon remand, along with MDL filings pertinent to the remanded case.

INTRODUCTION

Aredia® and Zometa® are prescription drugs manufactured and sold by Novartis Pharmaceuticals Corporation ("NPC"). The actions consolidated in MDL 1760 are pharmaceutical product liability suits alleging that NPC's products Aredia® and Zometa® caused injury, specifically

osteonecrosis of the jaw ("ONJ"). General causation and specific causation are among the issues contested in these lawsuits. Aredia® (pamidronate) and Zometa® (zoledronic acid) are FDA-approved intravenous bisphosphonate drugs typically prescribed by oncologists to prevent bone pain, fracture and other skeletal complications in patients with cancer that has metastasized to bone. The United States Food and Drug Administration ("FDA") approved Aredia® for the treatment of hypercalcemia of malignancy ("HCM") in 1991 and subsequently approved it for the treatment of multiple myeloma in 1995 and osteolytic bone metastases associated with breast cancer in 1996. FDA first approved Zometa® in 2001 for the treatment of HCM and in February 2002 for the treatment of multiple myeloma and bone metastases associated with breast cancer, prostate cancer, and other solid tumor cancers.

GENERAL MATTERS

1. Creation of the *In re Aredia®/Zometa®* MDL No. 1760

Before the creation of this MDL, claimants nationwide brought thirty-five actions against four manufacturers of bisphosphonate drugs: NPC, Merck & Co., Inc. ("Merck"), Proctor and Gamble Pharmaceuticals, Inc. ("P&G"), and Sanofi-Aventis U.S. LLC ("Aventis"). *See* Docket No. 1.[1] Certain Plaintiffs moved for coordinated or consolidated pretrial proceedings through an MDL. (Docket No. 1). NPC objected to the formation of a MDL to resolve these actions but endorsed transfer to the Middle District of Tennessee if consolidation was to occur. (Docket No. 1).

On April 18, 2006, the Judicial Panel on Multidistrict Litigation ("JPML") consolidated for pretrial management in the Middle District of Tennessee actions against NPC presenting factual

[1] The pre-MDL litigation consisted of fifteen actions pending in the Eastern District of New York, fifteen actions in the Southern District of New York, four actions in the Middle District of Tennessee, and one action in the Western District of Oklahoma. (Docket No. 1).

questions regarding (1) "the development, testing, manufacturing and marketing of the two [NPC] drugs" and (2) NPC's "knowledge concerning their alleged adverse effects, in particular, the potential for each drug to cause" ONJ. (Docket No. 1).[2] At the time the JPML centralized this litigation in the Middle District of Tennessee, three putative class actions involving Aredia® and Zometa® were pending in this District. April 19, 2006 JPML Transfer Order (Docket No. 1). None of the Plaintiffs resided in this District.

Since the inception of MDL 1760, this multidistrict litigation has consolidated more than 650 cases for pretrial management. The Court has ruled on two "waves" of dispositive and *Daubert* motions. The Court dismissed the cases in which summary judgment was granted and suggested remand in the cases in which summary judgment was denied. Thereafter, the Court suggested remand in eleven cases in which summary judgment motions were fully briefed but not decided. The JPML found that remand of those actions was appropriate, noting that the pendency of dispositive motions does not bar remand when continued inclusion of the actions in the MDL would not serve the purposes of 28 U.S.C. § 1407. *See* Docket No. 4395.

As of June 1, 2011, twenty-three cases had been remanded to transferor courts. Of these, two have proceeded to jury verdict, one for the plaintiff and one for NPC.[3] Five cases are currently set

[2] New Jersey state courts have also centralized a number of Plaintiffs' New Jersey state actions involving Aredia® and Zometa®. *See In re Zometa®/Aredia® Litig.*, Case No. MT 278.

[3] *Fussman v. Novartis Pharmaceuticals Corp.*, 1:06-cv-00149 (M.D.N.C.) (verdict for Plaintiff); *Hogan v. Novartis Pharmaceuticals Corp.*, 1:06-cv-00260 (E.D.N.Y.) (verdict for NPC).

for trial in 2011,[4] and four cases are set for trial in 2012.[5] In addition, two cases have been tried in state courts, with one verdict for each side.[6]

2. Parties and Representative Counsel

The Plaintiffs[7] have been collectively represented by the Plaintiffs Steering Committee (the "PSC"), the current members of which are: F. Dulin Kelly of Kelly, Kelly & Allman; Robert G. Germany of Pittman, Germany, Roberts & Welsh, LLP; Bart T. Valad and John J. Vecchione of Valad and Vecchione, PLLC; Annesley H. DeGaris of Cory, Watson, Crowder & DeGaris, PC; and Robert K. Shelquist of Lockridge, Grindal, Nauen, PLLP. Plaintiffs' Liaison Counsel is C. Patrick Flynn of Flynn and Radford Attorneys, PC. (Docket Nos. 87, 2072, and 3040).[8]

Defendant NPC is the only defendant in this MDL. Defendant NPC is represented in the MDL proceedings by Katharine Latimer and others at the law firm of Hollingsworth LLP. Two

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[4] *Deutsch v. Novartis Pharmaceuticals Corp.*, 2:09-cv-04677 (E.D.N.Y.) (trial set for 6/20/11); *Brodie v. Novartis Pharmaceuticals Corp.*, 4:10-cv-00138 (E.D. Mo.) (trial set for 7/18/11); *Baldwin v. Novartis Pharmaceuticals Corp.*, 2:06-cv-04049 (W.D. Mo.) (trial set for 9/26/11); *White v. Novartis Pharmaceuticals Corp.*, 2:06-cv-00665 (E.D. Ca.) (trial set for 10/4/11); and *Talley v. Novartis Pharmaceuticals Corp.*, 3:08-cv-00361 (W.D. N.C.) (trial set for 10/8/11).

[5] *Eberhart v. Novartis Pharmaceuticals Corp.*,1:08-cv-2542 (N.D. Ga.) (trial set for 1/9/12); *Kyle v. Novartis Pharmaceuticals Corp.*, 1:06-cv-0035 (W.D. Ky.) (trial set for 1/9/12); *McDaniel v. Novartis Pharmaceuticals Corp.*, 2:08-cv-2088 (W.D. Ark.) (trial set for 2/6/12); and *Brown v. Novartis Pharmaceuticals Corp.*, 7:08-cv-0130 (E.D. N.C.)(trial set for 2/21/12).

[6] *Stevens v. Novartis Pharmaceuticals Corp.*, No. DV-08-100 (Mont. Fourth Judicial District Ct., Missoula Co.) (verdict for Plaintiff); *Bessemer v. Novartis Pharmaceuticals Corp.*, Docket No. MID-L-1835-08-MT (N.J. Middlesex County Ct.) (verdict for Defendant).

[7] On December 26, 2007, the Court severed three claims with multiple Plaintiffs, *Fussman*, *Davids*, and *Earp*, into separate actions. (Docket No. 945).

[8] The Court entered a Fee and Expense Assessment Order, which was later amended. (Docket Nos. 2219, 2428). To date, no account has been opened, no trustee has been appointed, and no funds have been allocated under this Order.

additional MDLs have been created for claims related to Fosamax[9] and for claims against generic manufacturers.[10]

3. Referral of Discovery to Magistrate Judge

Judge Campbell referred all non-dispositive pretrial matters to Magistrate Judge Joe Brown. (Docket No. 2).

4. Primary Case Management Order

On July 28, 2006, the Court issued a Case Management Order ("CMO"), which applies to all pending MDL cases as well as subsequent cases filed in, removed to, or transferred to the Court as part of the MDL. *See* Docket No. 89. The CMO is the starting point regarding procedures and obligations of the parties in this MDL. The CMO sets forth a statement of jurisdiction and venue, the status of service and responsive pleadings, and the parties' theories of the case. (Docket No. 89). The CMO governs the procedures for motions practice, substitution of Plaintiffs, and pre-trial proceedings. (Docket No. 89). The CMO also explains the discovery to take place in the MDL, along with procedures for engaging in discovery. (Docket No. 89). Finally, the CMO sets forth an initial schedule for resolution of the cases. (Docket No. 89).

Over the course of the litigation, the CMO has been amended regarding various issues. In August 2006, the Court amended the CMO to allow Plaintiffs additional time, sixty days, to file

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[9] The JPML declined in 2006 to transfer Plaintiffs' actions pending against Merck, P&G, and Aventis to this MDL. (Docket No. 1). Subsequently, on August 16, 2006, the JPML created MDL 1789 in the Southern District of New York consolidating ONJ claims against Merck related to its drug Fosamax®. (JPML Docket No. 24).

[10] Pamidronate (sold by NPC under the brand name Aredia®) has been available in generic form from manufacturers other than NPC since 2001. Generic manufacturers are not parties to MDL 1760. On July 27, 2010, the JPML consolidated claims against generic manufacturers in the Eastern District of New York and created *In re Pamidronate Products Liability Litigation*, MDL No. 2120. (Docket No. 3414).

suggestions of death.[11] (Docket No. 103). In January 2008, the Court amended the CMO to allow NPC a potential product identification defense. (Docket No. 1066).

5. Conferences and Alternative Dispute Resolution

As parties agreed that settlement was unlikely, the Court did not initially attempt to set up alternative dispute resolution. *See* Docket No. 89. As the litigation progressed, the parties did participate in several mediation sessions with a mediator selected by the parties and the Court, John W. Perry, Jr. of Perry, Atkinson, Balhoff, Mengis & Bruns, LLC. Those mediation sessions have not proven successful to date.

6. Management of the Docket

In general, all documents are filed in the MDL 1760 docket. For documents that relate to a specific case or cases, they are also generally filed in the specific case docket as well. Unfortunately, the docketing process in this case has been difficult, and there may have been deviations from these general rules. For the most complete and accurate docket sheet, both the individual case and the MDL 1760 dockets should be reviewed.

DISCOVERY

1. Class Actions Discovery

Before the formation of the MDL, Plaintiffs filed three substantively identical putative class actions in the Middle District of Tennessee, one for Plaintiffs who received only Aredia® (*Wood*), one for Plaintiffs who received only Zometa® (*Becker*), and one for Plaintiffs who were infused with

[11] Plaintiffs' counsel have repeatedly been warned about the frequent delay in filing suggestions of death and motions for substitution. In a May 5, 2011 Order, the Magistrate Judge directed the PSC to remind all counsel of substitution requirements when a Plaintiff dies, and to insure that when motions to substitute are filed that they include appropriate documentation from the state court that the person designated for substitution is appropriately qualified under state law. (Docket No. 4478).

both (*Anderson*). *See* Docket No. 89. The Court ordered that discovery in the putative class actions and seven additional cases (five selected by Defendant, two selected by Plaintiffs) would occur in two phases.[12] The first, addressing class certification, began primarily with the production of Plaintiff Fact Sheets ("PFSs") by September 15, 2006, by all class Plaintiffs and Plaintiffs in the additional seven cases which included class action allegations. The CMO stated that the second phase of discovery, the "Merits Phase," could begin on July 2, 2007. The Court initially titled this first group of collective Plaintiffs "Wave One Plaintiffs." (Docket No. 89).

2. Discovery of NPC

In addition to the discovery discussed above, Plaintiffs were given leave to serve twenty-five additional interrogatories, to request production of documents, and to take depositions of fifty of Defendant's current and former employees. (Docket Nos. 89, 279). In response to the PSC's written discovery requests, Defendant estimates that through 2010 it has produced approximately sixteen million pages of hard-copy and electronic documents.[13] Between the MDL and the consolidated state court litigation in New Jersey, sixty-six depositions were taken of NPC current or former employees, and NPC produced a total of fifty-four deponents for those sixty-six depositions. These depositions occurred from 2006 through 2010. Many, but not all, depositions conducted under the auspices of

[12] The CMO stayed discovery in all cases outside of the "original three" putative class actions and the additional seven test cases until July 2, 2007. (Docket No. 89).

[13] Defendant produced non-privileged or otherwise protected responsive documents in electronic image form. Each document's electronic image conveyed the same information and image as the original document. Each page of a document was scanned by NPC into an image and if a document was more than one page, the unitization of the document was maintained. Each page of a produced document also had a legible, unique page identifier ("Bates Number") electronically "burned" onto the image by NPC. Each document also had a "confidential" legend electronically "burned" onto the image at the bottom of each page. NPC has agreed to provide, at the time of trial, "clean" copies of all documents that Plaintiffs intend to use at trial as indicated by the exhibit list the parties exchange pursuant to the final pre-trial order or other Court order.

either this MDL or the NJ Mass Tort litigation have been cross-noticed in the other coordinated proceeding.

The depositions and documents referred to above are available to Plaintiffs' counsel through the PSC. All such requests should be directed to the PSC's liaison counsel, Patrick Flynn.

3. Discovery of Plaintiffs

Defendant was entitled to discovery in each separate MDL case via service of a PFS and medical records authorization forms. (Docket No. 89). NPC also had the right to serve interrogatories in each case. The CMO sets forth the protocol for service of these discovery documents and for motion practice in the event CMO obligations were not met. Each Plaintiff was required to complete a PFS in all material respects and serve the PFS upon Defendant's Lead Counsel and counsel of record.[14] Plaintiffs were also to provide applicable accompanying medical record authorizations within forty-five days of service of the PFS. Once a PFS was served, Defendant was entitled to propound and serve on that Plaintiff five interrogatories and requests for production.

4. Third Party Discovery

In each case placed in a wave for discovery, Defendant and Plaintiffs were entitled to conduct fifteen depositions of non-parties per the CMO. (Docket No. 89). This number includes treating physicians. The Court held that treating physicians are fact witness to which both parties should have access. *See* Docket No. 1094. Accordingly, NPC could engage in *ex parte* communications with treating physicians as set forth in the Order.

5. Protective Order

[14] There have been ongoing problems with Plaintiffs' failure to timely serve the PFS, and NPC has sought to dismiss several cases on this basis.

On August 16, 2006, the Court entered a Protective Order governing the designation, handling, use and disclosure of confidential discovery materials. *See* Docket No. 100.

6. The Identification of Case Waves for Discovery

The Court has designated five waves of cases for discovery purposes (Waves I-A, I-B, I-C, II, and III), with a sixth wave (Wave IV) anticipated soon after the date of this Order. *See* April 18, 2011 Order (Docket No. 4412). The Court set deadlines in each wave for fact discovery, expert discovery, and *Daubert* and dispositive motions. In the later waves, the Court proposed larger numbers of cases to proceed to dispositive motions and condensed the discovery schedules. Supervision of discovery in the later waves continues.

7. Other Discovery Issues

This Court has presided over many discovery disputes between the parties and makes no attempt to summarize those rulings here. Certain rulings that may be particularly pertinent in subsequent proceedings are as follows:

Expert Discovery: The Court modified the CMO to provide one initial deposition of 14 hours for an expert who was noticed as an expert in more than five MDL cases, with any subsequent case-specific depositions of such experts limited to two hours, absent a showing of extraordinary need (Docket No. 3266). In Wave I-B, the Court ruled that there would be no further depositions of Plaintiffs' case-wide experts unless and until such expert(s) filed a Supplemental Report (Docket No. 3346).

Reclast®:[15] The Court declined to require NPC to produce all information concerning Reclast®/Aclasta® and required NPC instead to produce information on the safety of zoledronic acid regardless of whether it is contained in Zometa® data or Reclast® data. (Docket No. 1106).

Discovery of NPC: The Court denied Plaintiffs' motion to compel production of email from additional corporate employee custodians and denied NPC's motion to set a general cutoff for discovery against NPC. (Docket No. 1594).

De Bene Esse Depositions: The parties have taken certain *de bene esse* depositions in anticipation that these depositions may be needed for use at trial. Nothing in this Order is intended to prevent the parties from seeking additional *de bene esse* depositions and nothing in this Order is intended to address the admissibility of any *de bene esse* deposition in any particular trial.

SPECIFIC ORDERS/RULINGS

1. Class Certification

Plaintiffs withdrew their Motion for Class Certification of the personal injury claims and instead sought certification of various classes of Plaintiffs for dental monitoring. The Court denied Plaintiffs' Motion for a dental monitoring class. (Docket Nos. 693 and 694.)

2. Causation

The Court found that there are genuine issues of material fact as to general causation - that is, whether Aredia and Zometa cause ONJ generally. (Docket Nos. 2763 and 2764.) The Court dismissed certain cases for lack of specific causation experts.

3. Adequacy of Warnings

[15] Reclast® and Zometa® contain the same active ingredient, zoledronic acid, but they appear to have been prescribed for different medical purposes.

The Court found that there are genuine issues of material fact as to whether Novartis' warnings concerning Aredia and Zometa were adequate. (Docket Nos. 2766 and 2767.)

4. Statutory Presumptions and Preemption

The Court found that Florida law created a rebuttable presumption of no liability[16] which could not be rebutted by claims of fraud on the Federal Drug Administration ("FDA") because such claims were preempted,[17] but which could be rebutted with evidence that the products were defective and unreasonably dangerous. (Docket Nos. 2788 and 3131.)

The Court found that Michigan law immunized drug manufacturers from products liability subject to two exceptions[18] and that attempts to prove the exceptions, both of which involve fraud on the FDA, were preempted. (Docket No. 1273.)

The Court found that Texas law created a presumption of no liability on failure to warn claims if the product is FDA approved[19] and that attempts to rebut that presumption by showing fraud on the FDA were preempted. (Docket No. 1478.)

5. Non-U.S. Citizens

The Court dismissed the claims of Plaintiffs who were citizens of/treated in countries where Novartis does not market, distribute or sell Aredia and Zometa. (Docket Nos.1915, 2978 and 3230.)

6. Various state law claims

The Court found that breach of express warranty and negligence *per se* claims should be dismissed under the laws of certain states. *See, e.g.,* Docket Nos. 2777, 2781, 2785, 2792, 2796, 2800, 4049, 4053, 4065, 4067 and 4070.

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[16] Fla. St. Ann. § 768.1256(1).
[17] *Buckman Co. v. Plaintiffs' Legal Committee*, 121 S.Ct. 1012, 1017 (2001).
[18] Mich. Comp. Laws, § 600.2946(5).
[19] Tex. Civ. Prac. & Rem. Code Ann. § 82.007.

7. Expert Witnesses

The Court found that the testimony of Plaintiffs' expert Dr. Robert Marx was admissible, for purposes of summary judgment, on the issues of causal connection and treatment and preventative measures for ONJ. (Docket No. 2814.)

The Court found that the testimony of Plaintiffs' expert Dr. Keith Skubitz was admissible, for purposes of summary judgment, on the issues of general causation and accuracy of warnings. (Docket No. 2810.)

The Court found that the testimony of Plaintiffs' expert Dr. James Vogel was admissible, for purposes of summary judgment, on the issues of general causation and accuracy of warnings. (Docket No. 2811.)

The Court found the testimony of Defendant's experts Pendergrass, Stack, Stanton and Zimmerman to be admissible for purposes of summary judgment. (Docket No. 2828.)

DOCUMENTS TO BE SENT TO TRANSFEROR COURT

The Clerk of Court will forward to the transferor court, electronically where feasible, a copy of this Order, the docket sheet for MDL 1760, the docket sheet for each case being remanded, and the Joint Designation of the Contents of the Record to be Remanded, which document shall be filed jointly by the parties within fourteen (14) days of the JPML's remand in an individual case. The case-specific docket sheets will be deemed to include and incorporate all matters on the MDL 1760 docket sheet that refer or pertain to "all cases" or that otherwise refer or pertain to the particular case being remanded.

In the event a party believes that the docket sheet for a particular case being remanded is incorrect or incomplete for any reason, a party to that case may, with notice to all other parties to

the action, file with the transferor court a Designation Amending the Record. Upon receiving that Designation, the transferor court will make any needed changes to the docket. If the docket is revised to include additional documents, the parties will provide those documents to the transferor court.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE